FOCUS ON
CARDIOLOGIA INTERVENTISTICA

S-ICD: update 2021

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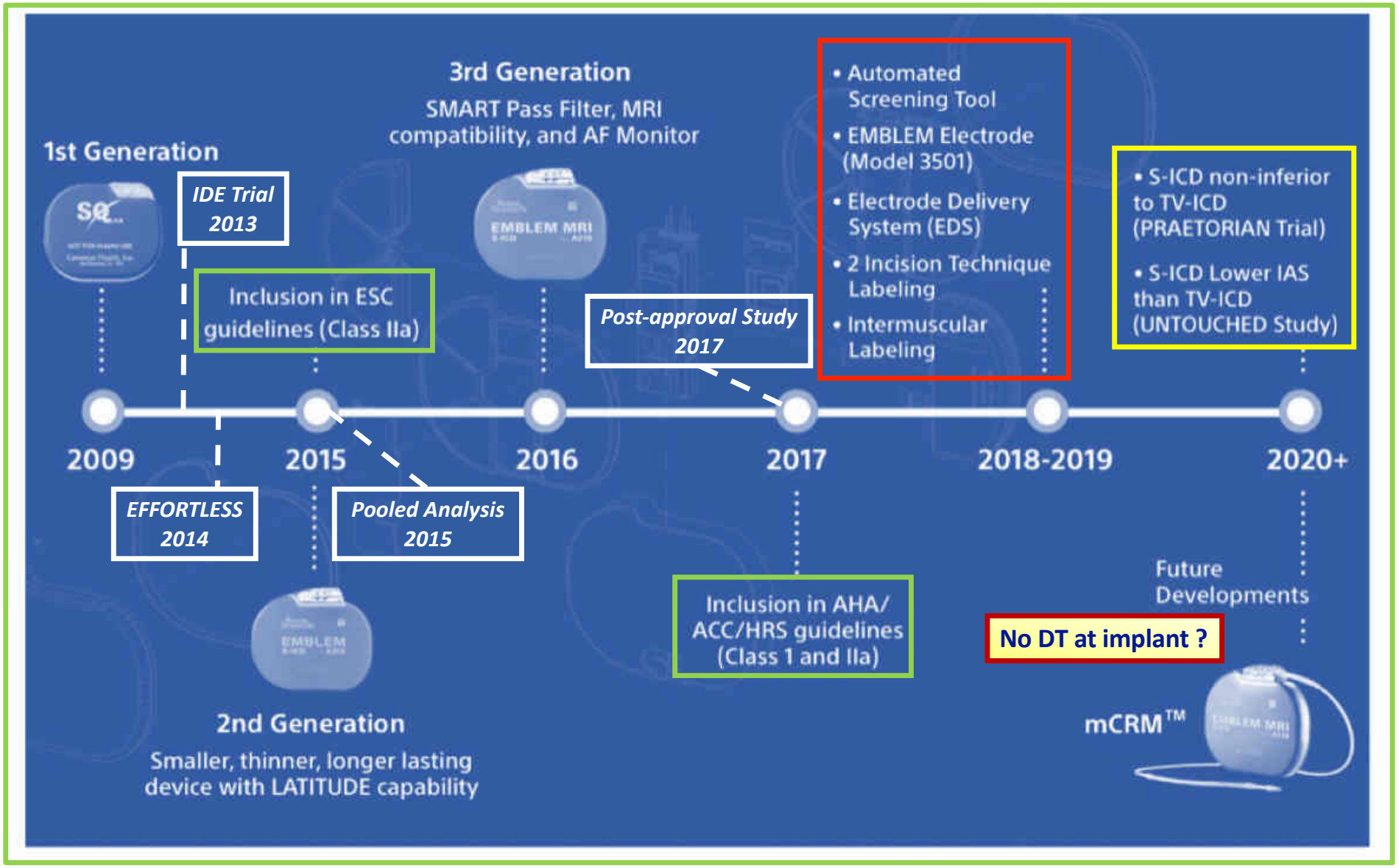
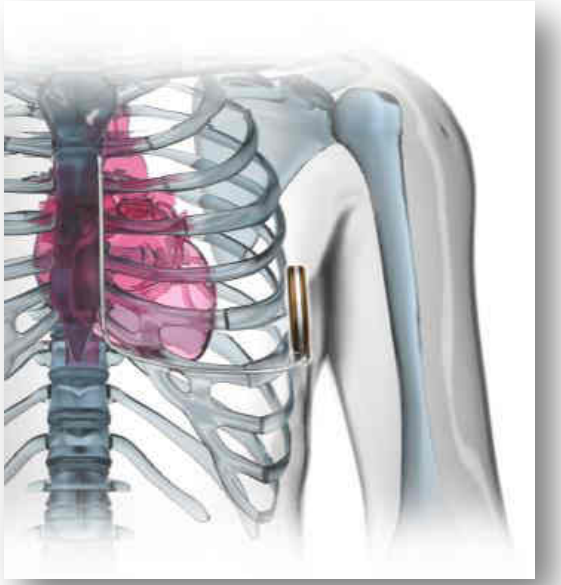

1st Generation
IDE Trial 2013
Inclusion in ESC guidelines (Class IIa)
EFFORTLESS 2014
Pooled Analysis 2015
2nd Generation
Smaller, thinner, longer lasting device with LATITUDE capability
3rd Generation
SMART Pass Filter, MRI compatibility, and AF Monitor
Post-approval Study 2017
Inclusion in AHA/ ACC/HRS guidelines (Class 1 and IIa)
• Automated Screening Tool
• EMBLEM Electrode (Model 3501)
• Electrode Delivery System (EDS)
• 2 Incision Technique Labeling
• Intermuscular Labeling
• S-ICD non-inferior to TV-ICD (PRAETORIAN Trial)
• S-ICD Lower IAS than TV-ICD (UNTOUCHED Study)
Future Developments
No DT at implant ?
mCRM™
2009
2015
2016
2017
2018-2019
2020+



- *Cassa attiva in posizione sottoascellare*
- *Catetere "solido" in posizione parasternale*
- *Shock bifasico **max output 80 Joule** (5 shock per episodio)*
- *Polarità shock adattativa (cambio di polarità in caso di shock inefficace)*
- *Tempo carica per 80 J: 14.6±2.9 s (real life: 9.6-29.7 s)*
- ***Post-shock pacing** (max 30 s)*

- ***No pacing antibradicardico***
- ***No ATP***

Who Should Receive the Subcutaneous Implanted Defibrillator?

The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing

Jeanne E. Poole, MD; Michael R. Gold, MD, PhD Circ Arrhythm Electrophysiol. 2013

2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

Subcutaneous implantable cardioverter defibrillator

Recommendations	Class[a]	Level[b]	Ref.[c]
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death

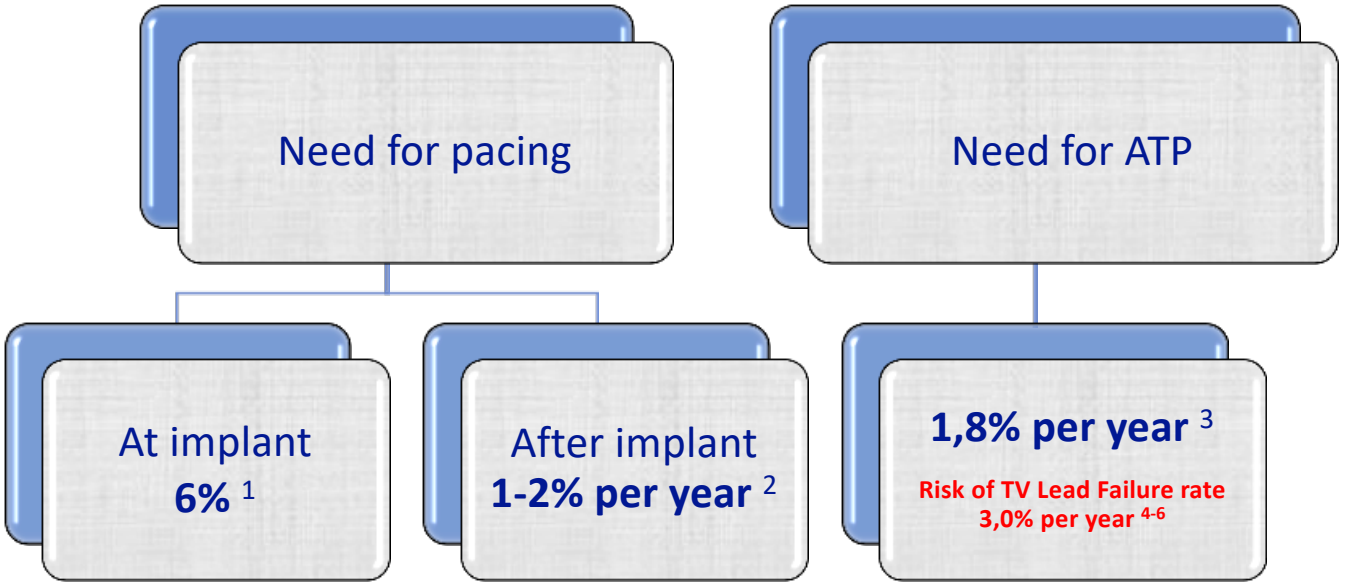
Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator

References that support the recommendations are summarized in Online Data Supplement 55.

COR	LOE	Recommendations
I	B-NR	1. n patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).

If is neither needed nor anticipated pacing for bradycardia or VT termination

What are the true pacing needs ?



S-ICD explant for pacing requirement	No. of patients
EFFORTLESS mid-term follow-up	1/985 (0.1 %)
Dutch 6 year follow up	1/118 (0.8 %)
Austrian Registry	2/236 (0.8 %)

1. *de Bie MK, et al. Heart 2013;99:1018–1023. doi:10.1136/heartjnl-2012-303349 (n=2712)*
2. *V Kutyifa. et al. The Need for Pacing in patients who qualify for and ICD: Clinical Implications. ESC abstract 2014*
3. *Poole, et al. Circulation Arrhythmia and Electrophysciology 2013; 6: 1236-1245*
4. *Kleemann et al. Ciculation 2007. 5. Atallah et al. Circulation 2013. 6. Borleffs et al. Circ Arrhythmia Electrophysiol. 2009*

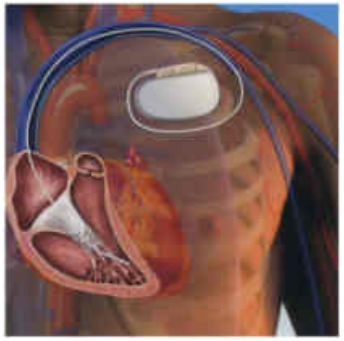
THE TRUE NEW QUESTION

Which patient

is not suitable

for S-ICD implantation ?

S-ICD vs TV-ICD



PRAETORIAN & UNTOUCHED

Trial Results

PRAETORIAN

A PRospective, rAndomizEd Comparison of subcuTaneOus and tRansvenous ImplANtable Cardioverter Defibrillator Therapy

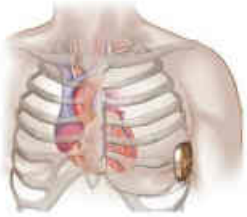
The NEW ENGLAND JOURNAL of MEDICINE

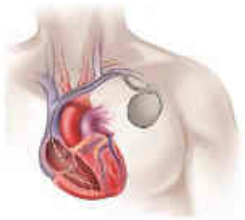
ORIGINAL ARTICLE

Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

Prospective Randomized Head-Head





From March 2011 through January 2017, a total of 876 patients enrolled and randomized

S-ICD group 426 pts

TV-ICD group 423 pts

Median duration of follow-up: 49.1 months

Primary endpoint:

- ***composite of device-related complications and inappropriate shocks***

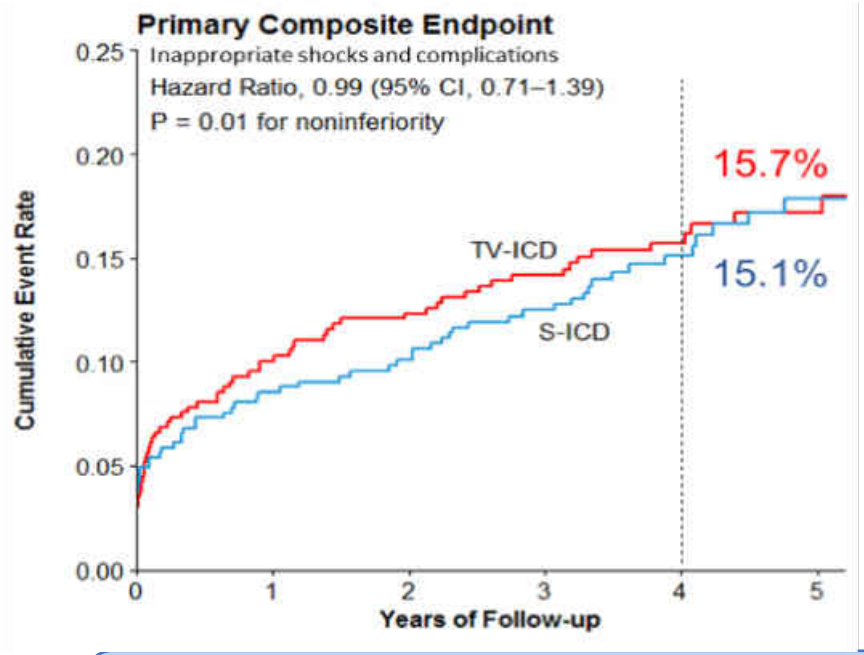
Secondary endpoints:

- ***death and appropriate shocks***

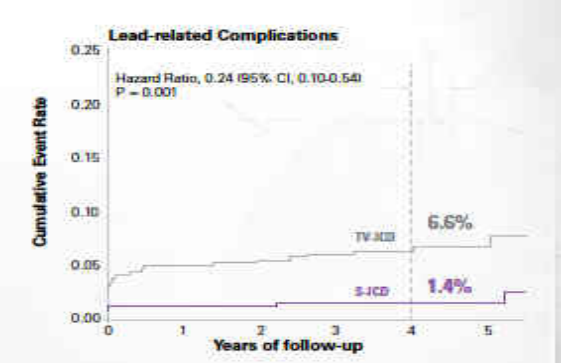
Knops R.E, et al N Engl J Med 2020

PRAETORIAN

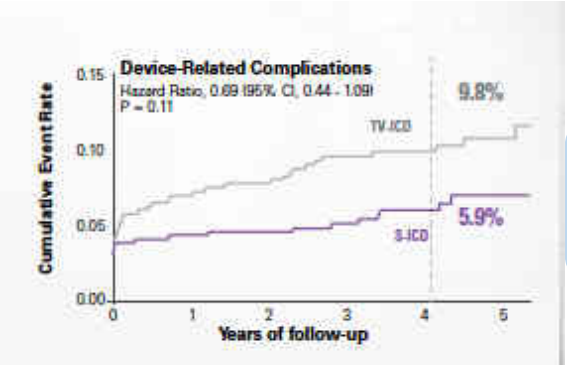
Primary Endpoint
Non-inferiority Demonstrated



The S-ICD was noninferior to the TV-ICD with respect to device-related complications or inappropriate shocks.



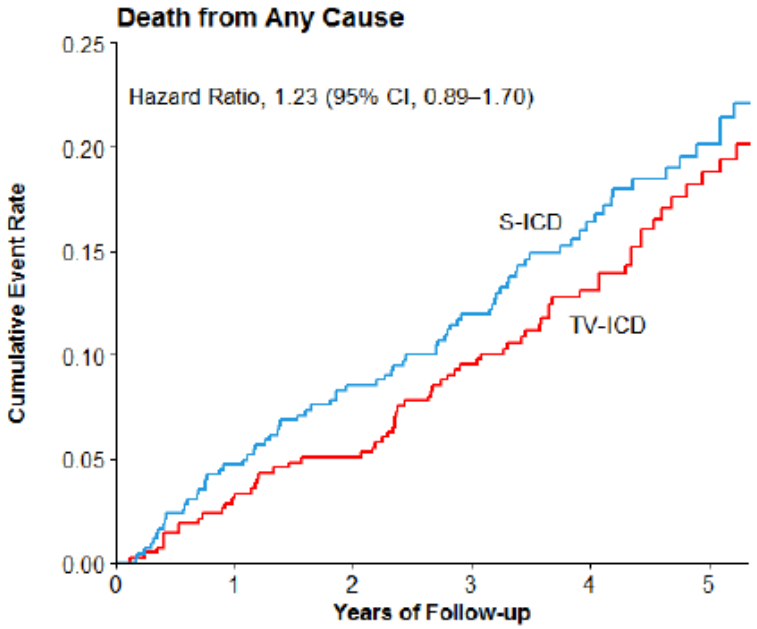
Significantly fewer lead-related complications
6.6% (n=24) in the TV-ICD arm vs 1.4% (n=5) in the S-ICD arm (P =0.001)
Close to 5 times as many patients experienced a lead complication in the TV-ICD arm



Trend for fewer device-related complications *expected to increase by 8 years in PRAETORIAN XL**

PRAETORIAN

Secondary Outcome



	S-ICD (n = 426)	TV-ICD (n = 423)
Death from any cause	83 (16.4%)	68 (13.1%)
–Sudden cardiac death	18	18
–Other cardiovascular death	34	28
–Noncardiovascular death	31	22

- **No between-group differences in the cumulative incidence of major adverse cardiac events.**
- Mortality rate was low both S-ICD and TV-ICD.
- **Sudden cardiac deaths were identical for S-ICD and TV-ICD**

The UNTOUCHED Study

Understanding Outcomes with the S-ICD In Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) Trial Primary Results

Circulation

ORIGINAL RESEARCH ARTICLE

Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial

Hypothesis:

The incidence of IAS for S-ICD in primary prevention, LVEF ≤ 35% patients will be non-inferior to the rate in TV-ICD patients with similar programming observed in MADIT-RIT high rate and long duration arms.

Global, multicenter, prospective, nonrandomized study

- De-novo 1.111 implanted patients enrolled at 110 sites from June 2015 to Decembre 2019
- Follow-up for 18 months
- Pre-specified, device programming with a conditional zone of 200 bpm and an aggressive shock zone of 250bpm.

Primary Endpoint

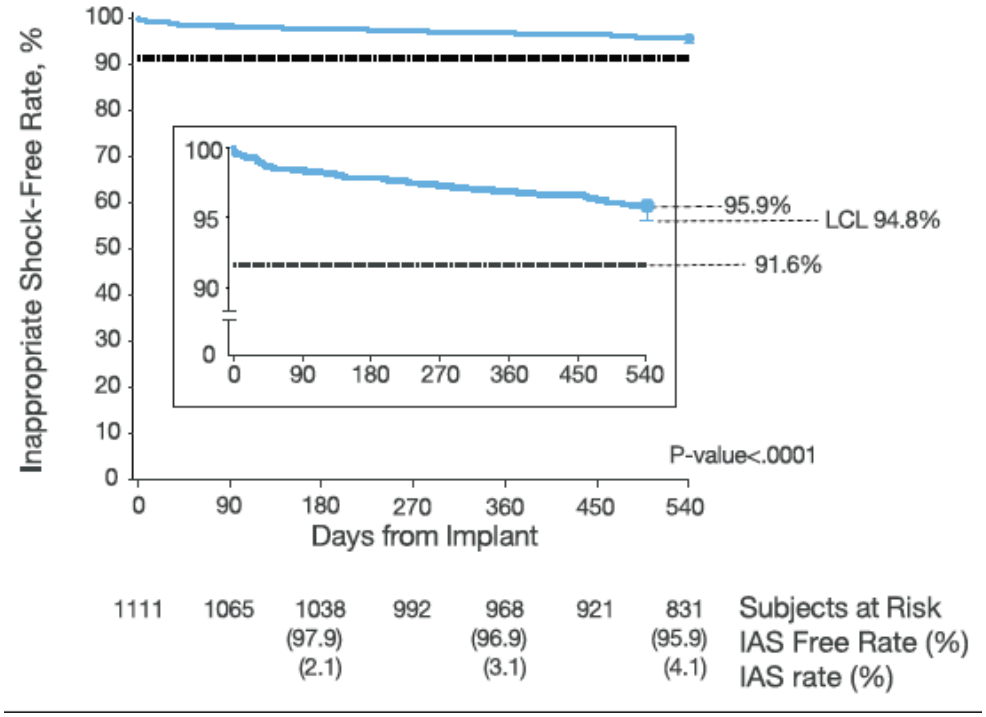
- Inappropriate Shock-free rate at 18 months: performance goal of **91.6%**
- Derived from MADIT-RIT IAS-free rate in Arms B and C: **94.6**%

Secondary Endpoints

- All Cause Shock-free rate at 18 months: performance goal of **85.8%**
- System and Procedure Related Complications at 30 days; previously reported

The UNTOUCHED Study

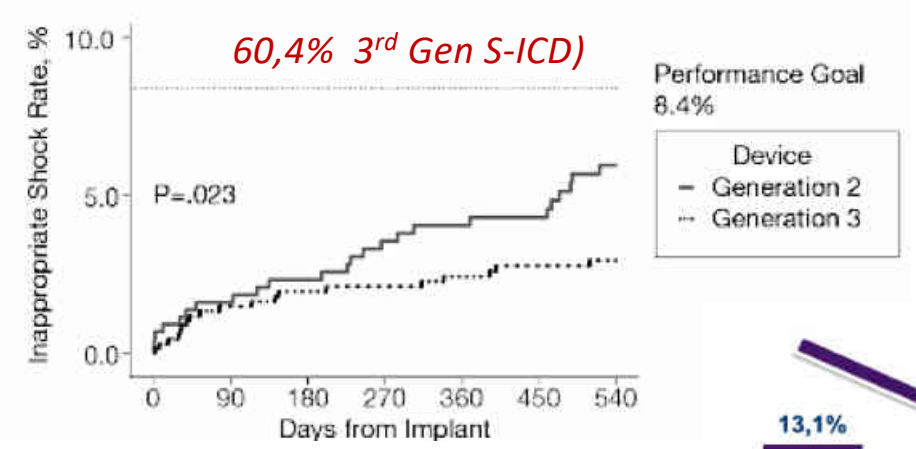
Primary Endpoint: Inappropriate Shock-Free Rate at 18 Months

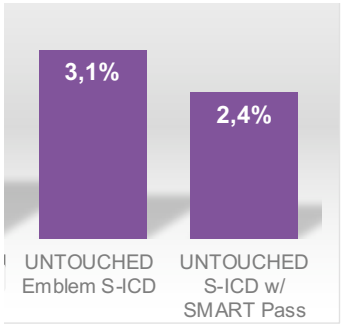


IAS-Free Rate 95.9%
95% Lower Confidence Limit (LCL) 94.8%
Performance Goal 91.6%
P-value<.0001

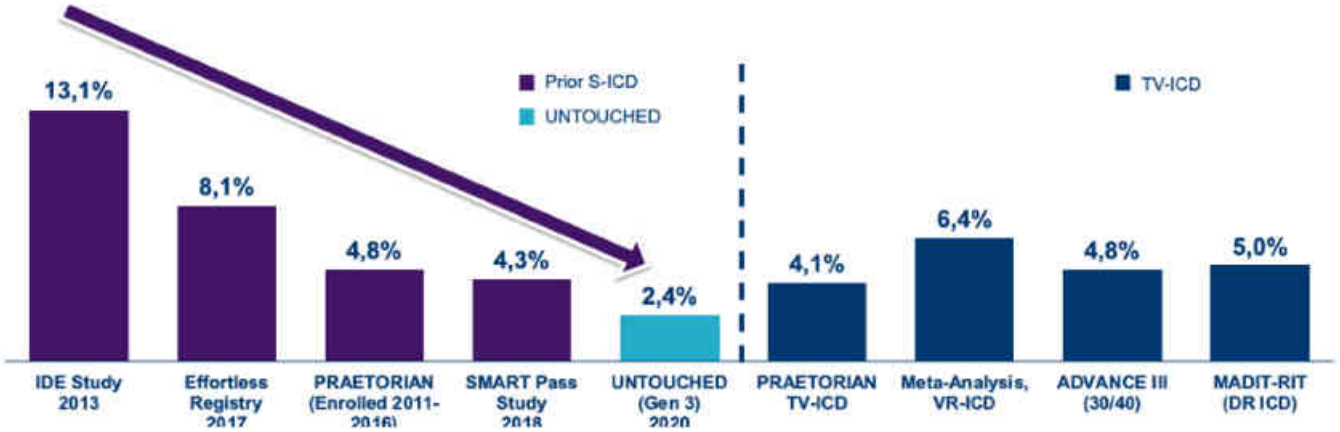
The UNTOUCHED Study

Inappropriate Shock Rate by Device Type





Rate of IAS for S-ICD continues to decline



The UNTOUCHED Study

Appropriate Therapy and Survival

Discrete Episodes: 64

- First shock success rate: 92.2%
- Final shock success rate: 98.4%
  - 1/64 final shock failed; converted spontaneously

VT Storms

- Seven subjects experienced 58 episodes in 9 storm events
- Final conversion rate for all storm events: 100%

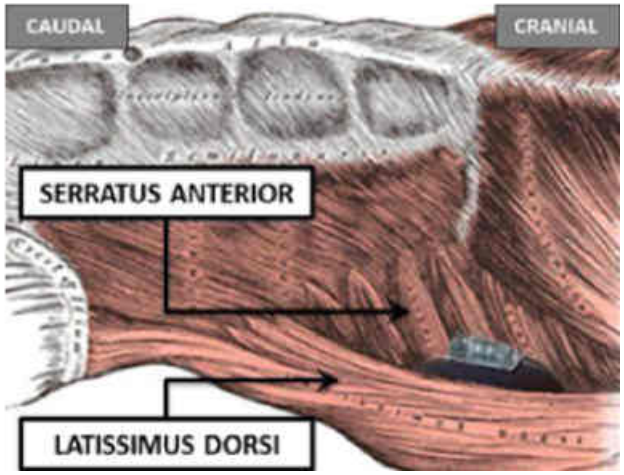
Mortality

- Overall Survival Rate: 94.9%; LCL 93.7%
- 57 deaths
- 4 arrhythmic deaths:
  - 2 pulseless electrical activity
  - 2 asystole

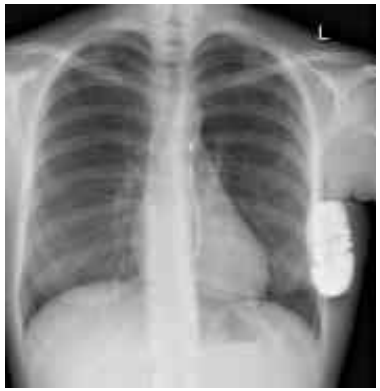
Causes of Death

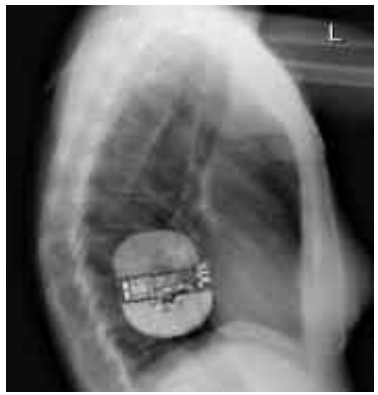
Cause of Death	Number of Patients
Cardiac	28
Arrhythmic	*4*
Ischemic etiology, N (%)	*2*
Pump Failure	*14*
Unknown	*8*
Non Cardiac	21
Unknown	8
Total	**57**

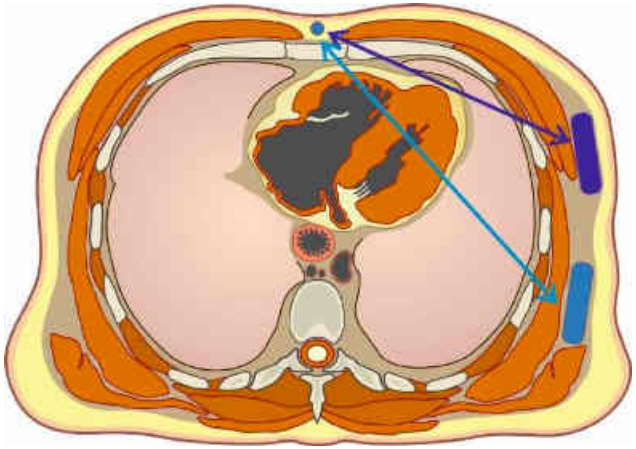
Advantage of Intermuscular Pocket technique



- *Optimal position for DFT and impedance measurements*
- *Reduced risk of pocket complications (erosion and infection)*
- *Reduced device migration*
- *Consistency in implant technique*
- *Enhanced patient comfort as the device is protected by the muscle layer*
- *Excellent cosmetic outcomes*
- *Intermuscular placement can be particularly beneficial in low and high BMI patients*



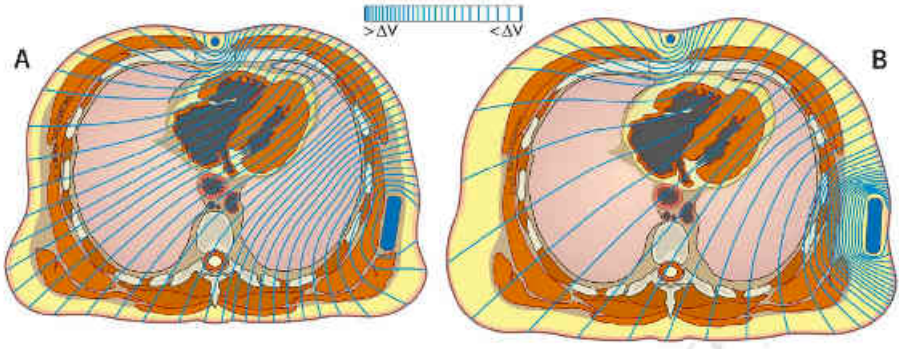




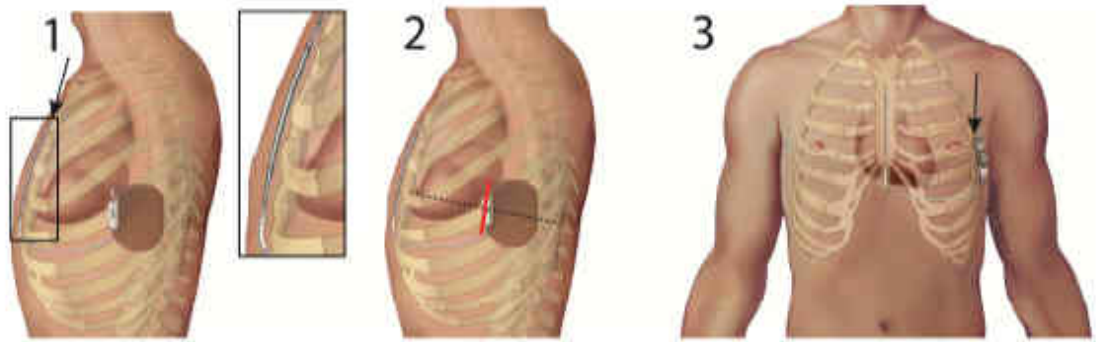
A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable defibrillator: the PRAETORIAN score

MD Anne-Floor B.E. Quast, Sarah W.E. Baalman, MD, Tom F. Brouwer, MD, L. Smeding, PhD, Arthur A.M. Wilde, MD PhD, Martin C. Burke, DO, Reinoud E. Knops, MD PhD

The PRAETORIAN SCORE is a non-invasive method to evaluate the S-ICD implant position



The isolating effect of fat tissue on the effective shock vector



Step 1)
Determine the number of coil widths of fat tissue between the **nearest** half of the S-ICD coil and the sternum or ribs.

≤ 1	coil-width	30
> 1 ≤ 2	coil-widths	60
> 2 ≤ 3	coil-widths	90
> 3	coil-widths	150

Step 2)
Determine the position of the S-ICD generator in relation to the mid-line (red line).

Generator is on or posterior of the mid-line	x 1
Entire generator is anterior of the mid-line	x 2
Entire generator is > 1/2 length anterior	x 4

Step 3)
Determine the amount of fat tissue between the **nearest** point of the generator and the thoracic wall.

< 1 generator-width	x 1
≥ 1 generator-width	x 1.5

Step 4)

PRAETORIAN score ≥ 90:

BMI ≤ 25 kg/m²	- 40
BMI ≥ 25 kg/m²	= Final score

Final PRAETORIAN score

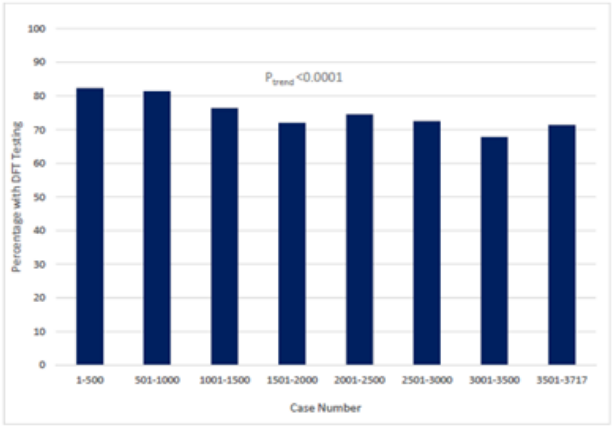
< 90	Low risk of conversion failure
90 < 150	Intermediate risk of conversion failure
≥ 150	High risk of conversion failure

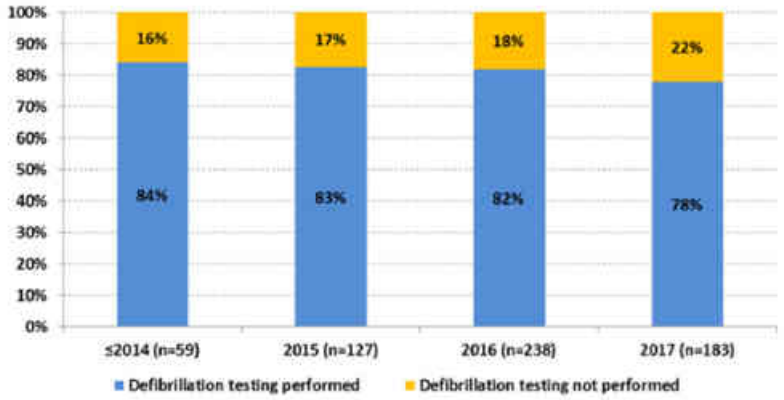
Conversion test at S-ICD implant: *to do or not to do ?*

Defibrillation efficacy testing (DT) is recommended at implantation of subcutaneous implantable cardioverter–defibrillators (S-ICD).

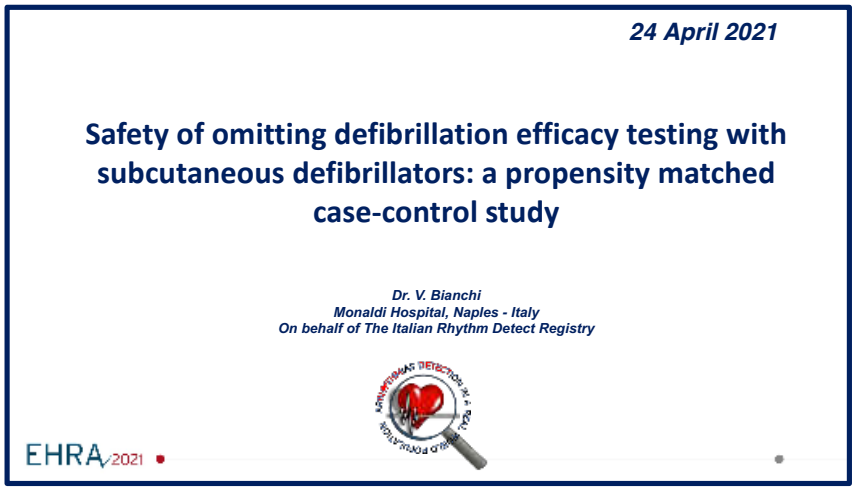
2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement	
Class I	Defibrillation efficacy testing is recommended in patients undergoing a subcutaneous ICD implantation (level C)

However, prior works [1,2,3] found that adherence to this recommendation is declining in clinical practice.





Use of DT over Time: from 82.4% to 71.4% between 2012 and 2015 (US) from 84% to 78% between 2014 and 2017 (IT) .



Aim

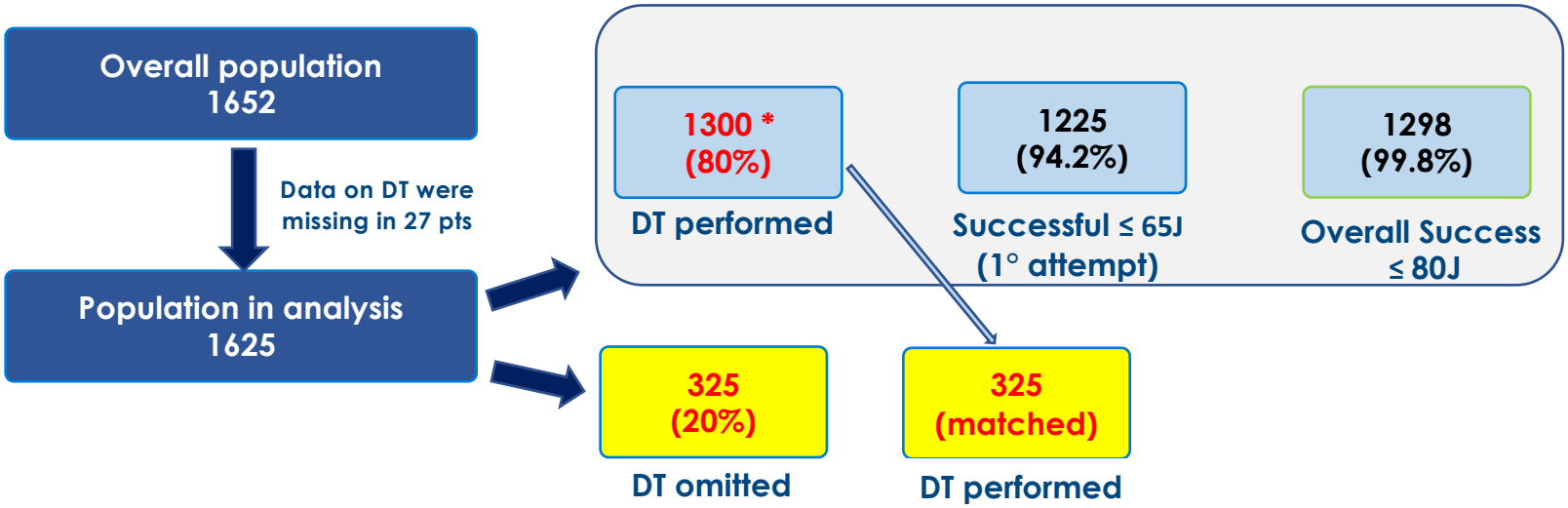
To compare:

- *survival from all-cause death and first ineffective shock (**primary endpoint**)*
- *the composite of all-cause death, ineffective shock, inappropriate shock and device-related complication (**secondary endpoint**)*

between patients who underwent DT and those with omitted DT

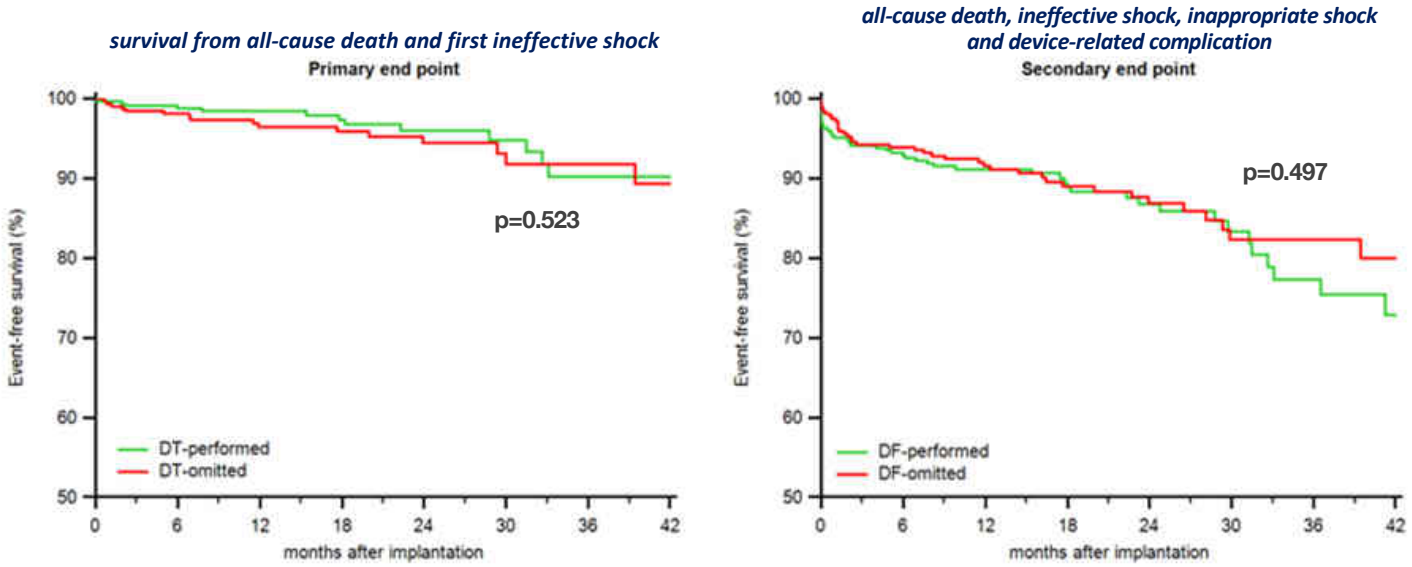
Methods

From January 2013 to December 2019, consecutive patients undergoing implantation of an S-ICD were enrolled at **60 Italian centers** in the ***Rhythm Detect Registry***



- ***In the 1300 patients who underwent DT, 2 (0.15%) episodes of electromechanical dissociation (1 fatal) as a consequence of testing were reported.***

Results



Kaplan–Meier estimates of time to the primary endpoint and secondary endpoint

There was no significant difference in the in the primary or in the secondary outcome between the two groups in analysis

Conclusions

- A strategy that ***omits DT did not appear to compromise the effectiveness of the S-ICD*** and no additional risk seems associated with DT omission at a mid-term follow-up.

- **The ongoing PRAETORIAN DFT trial will confirm this finding.**

Grazie per l'attenzione